

# **The electronic cigarette** (personal nicotine vaporizer)

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## Respects to the indigenous people and a note on pituri

- **In Australia** smokeless tobacco (**pituri**) has been gathered from certain shrubs and treated with ash for thousands of years, Tobacco leaf is chewed in other indigenous communities. (**Tom Calmo**) Pituri contains nicotine and appears to discourage protect some communities from smoking.
  - a) Pituri deserves **serious chemical and toxicological research**. What if any carcinogens are in pituri? Can they be removed? What else does it contain besides nicotine?
  - b) Pituri use could be **affirmed and protected** for indigenous communities.
  - b) Pituri be **investigated as a possible ally** in reducing the high tobacco smoking prevalence among indigenous communities.
  - c) **The rights of indigenous people to traditional drugs and remedies** such as pituri and patents deriving therefrom be protected in Australian law.
  - d) Although Australian law bans sale of smokeless tobacco, and taxes imports for personal use, **indigenous communities should be given the right to trade pituri** as a commodity if they wish, and pay no tax.

# NZ End game website

- [www.endsmoking.org.nz](http://www.endsmoking.org.nz)

End Smoking NZ trust founded 2006

Dedicated to the **phase-out of cigarette and tobacco sales** by 2020.

**Not prohibition:** no ban on home growing for personal use.

# E-cigarette research funding

- E-cigarette safety tests were funded by Ruyan through Health New Zealand Ltd, who then contracted with laboratories in New Zealand and Canada.
- Duke University, North Carolina and British American Tobacco research division (UK) contributed analyses at no cost.
- *Disclaimer:* Health NZ has no financial interest or otherwise benefits from any tobacco, pharmaceutical or nicotine company.

# Ruyan V8 classic e-cigarette



# E-cigarette, first of a new product class of flameless nicotine “cigarettes”

- Invented 2004 by Hon Lik
- Patent for atomiser owned by Ruyan
- Sells best in countries where cigarette prices and health concerns high.
- Operating temperature **54C maximum**
- Battery generates 0.1mW
- Propylene glycol 0.8 g /cartridge the solvent
- Nicotine 16 mg, 11mg, 6 mg, 0 mg /cartridge

More at [www.healthnz.co.nz/ecigarette](http://www.healthnz.co.nz/ecigarette)  
and at [www.endsmoking.org.nz](http://www.endsmoking.org.nz)

# The research question: Does it give a safe and satisfying smoke?

- **Marketed as cigarette substitutes;**
- Claim to deliver nicotine without smoke toxicants and the risks of smoking.

We ask:

- 1) Is this product safe – relative to cigarettes and in absolute terms?
- 2) Is this product efficacious? Does it relieve cravings and does it raise blood nicotine?

**Is this product safe – relative to cigarettes and in absolute terms?**

**Relative risk:** Is it safer than smoking?  
Emissions comparisons.

**Absolute risk:** Does it pose new risks?

**Other risks**      Child safe?  
Cross-infection?



# Laboratories involved

- **NZ:**
  - Environmental Science and Research Institute (ESR), Porirua.
  - Hort Research, Hamilton
  - Lincoln University, Canterbury .
  - Syft Analytics Ltd, Christchurch
  - Hills Laboratories, Hamilton
- **CANADA** Labstat International, Ontario, Canada
- **USA**
  - Center for Nicotine and Smoking Cessation Research, Duke University, NC, USA.
- **UK**
  - British American Tobacco Group R&D, UK.

# E-cigarette mist tested for 62 smoke toxicants: 11 measurable

- Aldehydes  
Acetaldehyde, butyraldehyde, crotonaldehyde,  
formaldehyde.
- Ketones:  
Acetone, methyl ethyl ketone
- Metal: Mercury
- Tobacco-specific Nitrosamines  
NNK, NNN NAT

# FDA doesn't know if e-cigarettes any better than cigarettes

- (E-smoker:} "This is something the government should be pushing for, a clean way of allowing people to smoke," Woessner said.
- Delancey (FDA) disagreed. "I feel their pain," she said. "We don't know if this (e-cigarette) is any better for them." (than cigarettes)
- Jim Merkel. Users love e-cigarettes but FDA wants to take a closer look. *St Louis Today* 30 Sep 2009  
<http://suburbanjournals.stltoday.com/articles/2009/10/01/south/news//0930sc-ecig0.txt>

# FDA findings on e-cigs July 2009

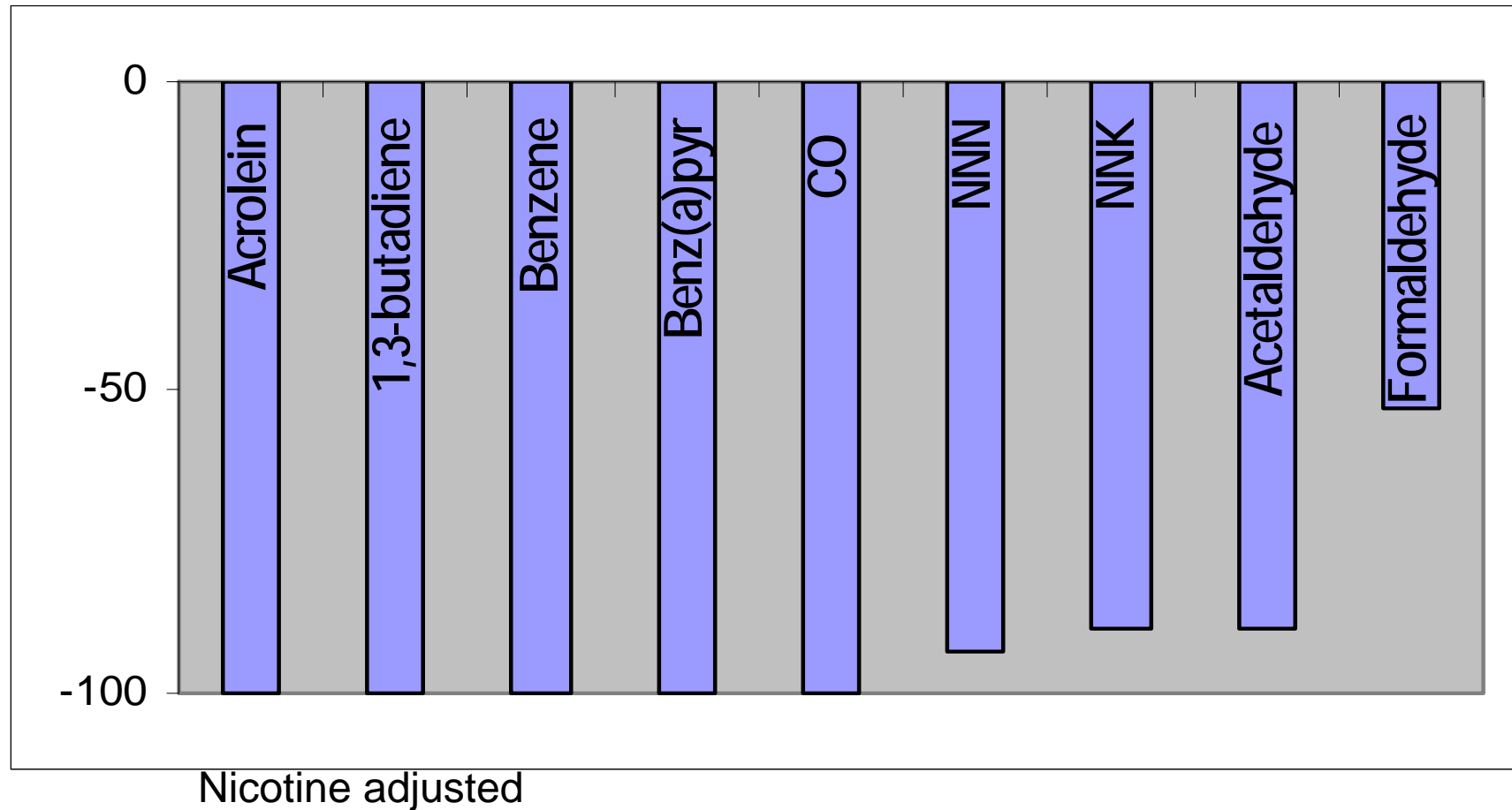
Released 25 Jul 2009- Preliminary report

- Variation between cartridges in nicotine dose.
- One cartridge of *Smoking Everywhere* brand contained about 1% diethylene glycol (DEG).
- Some cartridges contained traces of tobacco specific nitrosamines.
- *N-Joy* brands contained traces of nicotine impurities eg beta-nicotyrine.

# Carcinogens (TSNAs) in e-cigarettes - FDA

ng/g	TSNAs per piece	Maximum exposure / day
<b>Ruyan cartridge 16mg</b> <small>Labstat 2007</small>	8	8
<b>CQ patch 4 mg</b> <small>Stepanov 2006</small>	8	8
<b>Nicorette gum 4 mg</b> <small>Stepanov 2006</small>	2	24
<b>Marlboro Red regular</b> <a href="http://www.endsmoking.org.nz/snuffregulations.htm">www.endsmoking.org.nz/snuffregulations.htm</a>	6 600	81 200

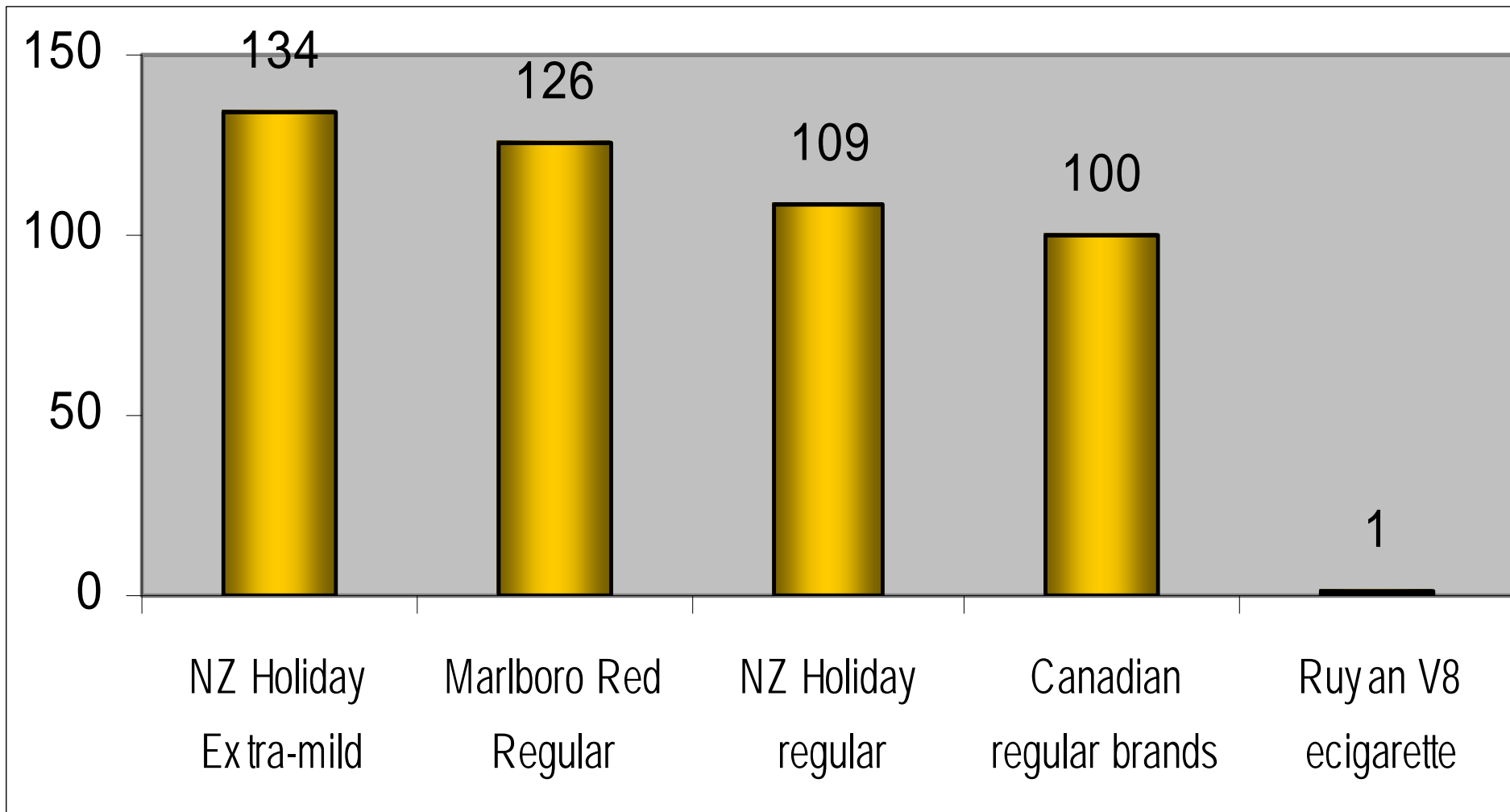
**FCTC mandated reductions for top 9 toxicants  
asked for by WHO TobReg  
in 2008: achievable now by e-cigarette**



## Toxicants levels in smoke >> mist

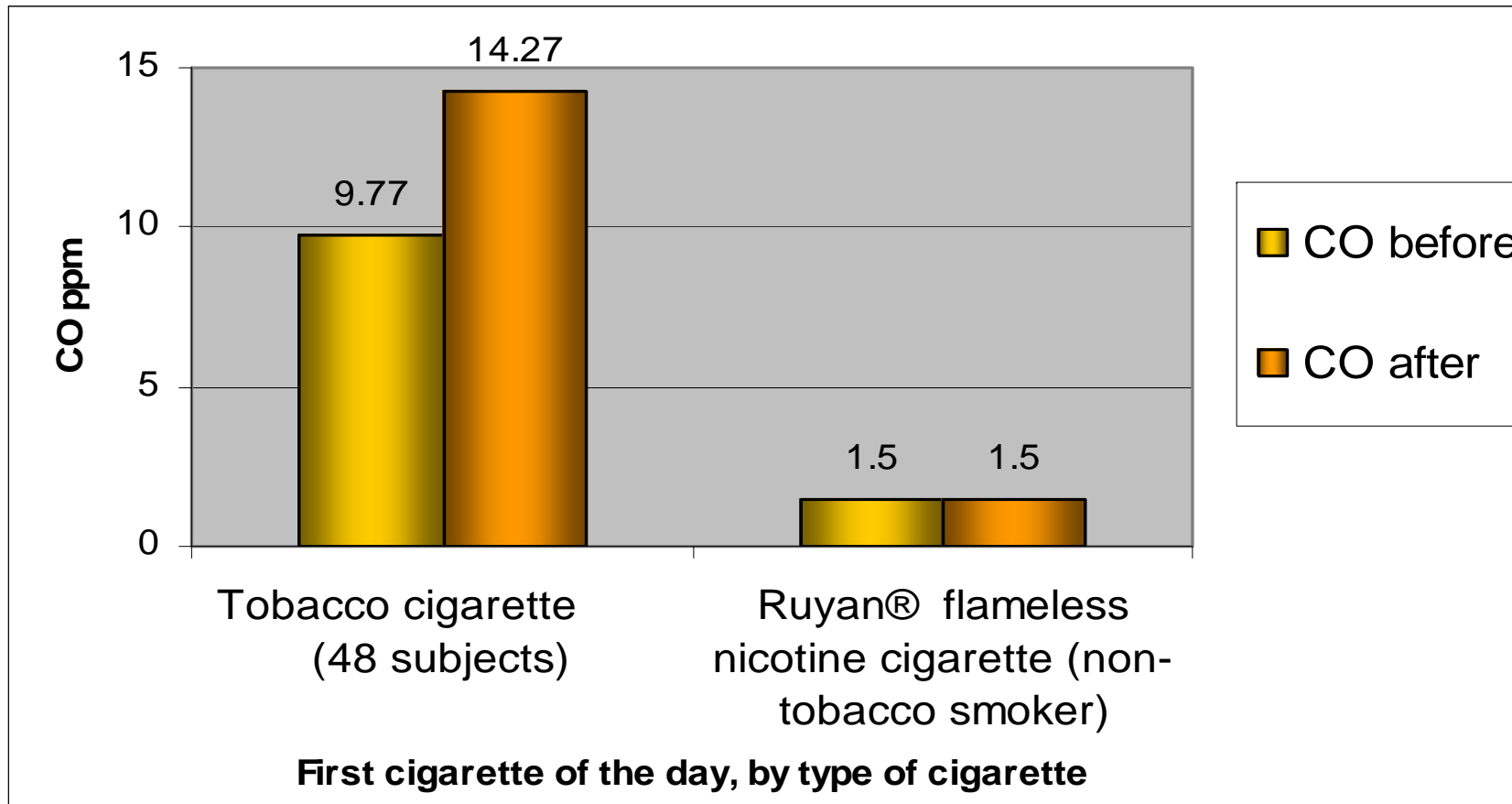
Per cigarette, or Per e-cigarette of same puffs	Marlboro Regular	E- cigarette
<b>Aldehydes      microg (ug)</b>		
Acetaldehyde	458	4
Butyraldehyde, Formaldehyde	29, 27	2
Crotonaldehyde	14	1
<b>Ketones              microg (ug)</b>		
Acetone, Me Et Ketone	262, 58	44
<b>NNN, NNK, NAT      ng</b>	<b>71,58, 64</b>	<b>0.5</b>
<b>Mercury                      ng</b>	2.8	0.17
<b>Chyrsene PAH              ng</b>	3.7	0.1

# Toxic emissions score adjusted for nicotine





# Cigarette smoking increases breath and alveolar CO: vaping does not



# The e-cigarette: low nicotine

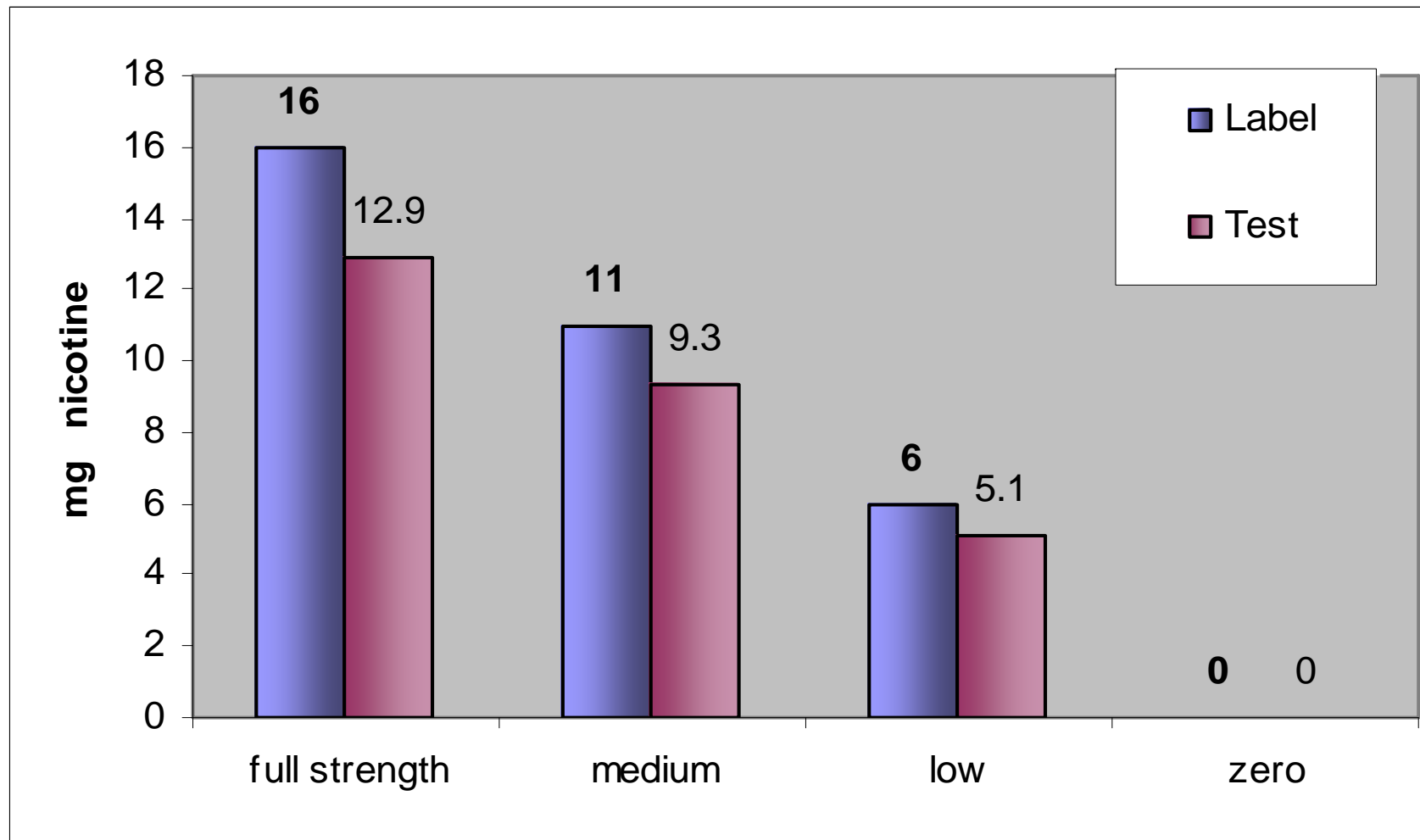
Active ingredient: Nicotine

Dose 10 micrograms / puff

Absorption site Upper respiratory tract

Count median diameter (CMD) 40 nm  
< cigarette CMD

# Nicotine content < label says



# Nicotine content

## similar across products

	Cigarette <i>Marlboro</i> Regular	NRT Inhaler <i>Nicorette</i>	E-cigarette <i>Ruyan</i>
Content	<b>13 mg</b> /cigarette	<b>10 mg</b> /cartridge	<b>13 mg</b> /cartridge
Nicotine purchased for 1 day's use	260 mg (1 packet)	60 mg (6 carts.)	13 mg (1 cartridge)

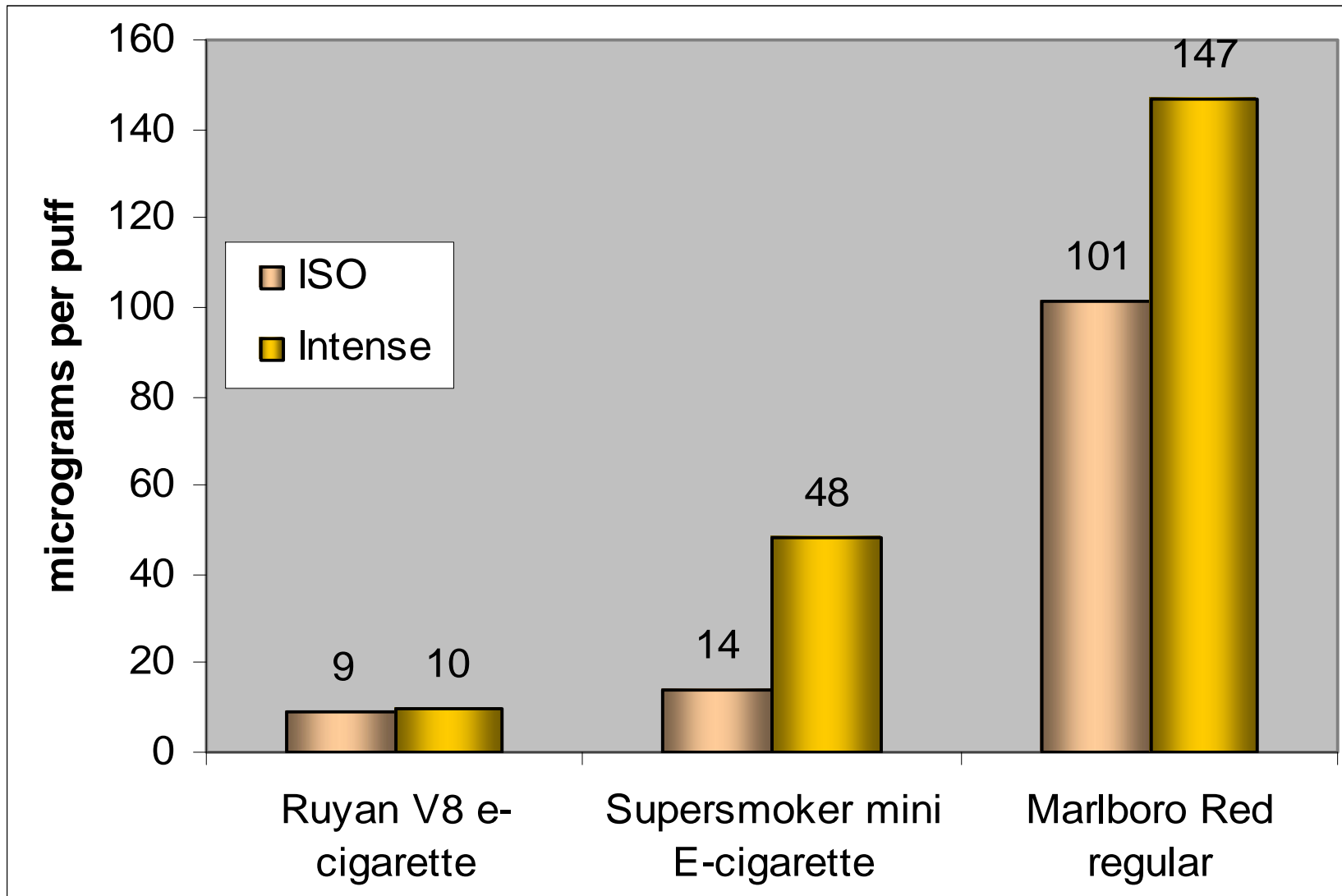
# Nicotine delivery

	Cigarette <i>Marlboro</i> Regular	NRT Inhaler <i>Nicorette</i>	E-cigarette <i>Ruyan</i>
Delivery / 35 ml puff	0.1 mg	0.01 mg	0.01 mg

# Nicotine content, delivery, absorption

	Cigarette <i>Marlboro</i> Regular	NRT Inhaler <i>Nicorette</i>	E-cigarette <i>Ruyan</i>
Delivery / 35 ml puff	0.1 mg	0.01 mg	0.01 mg
Absorption /10 puffs	1.0 mg	?0.05 mg	?0.05 mg
Absorption %	100%	? 50%	? 50%

# Nicotine per puff, mist v. smoke



# Clinical trial of e-cigarette efficacy

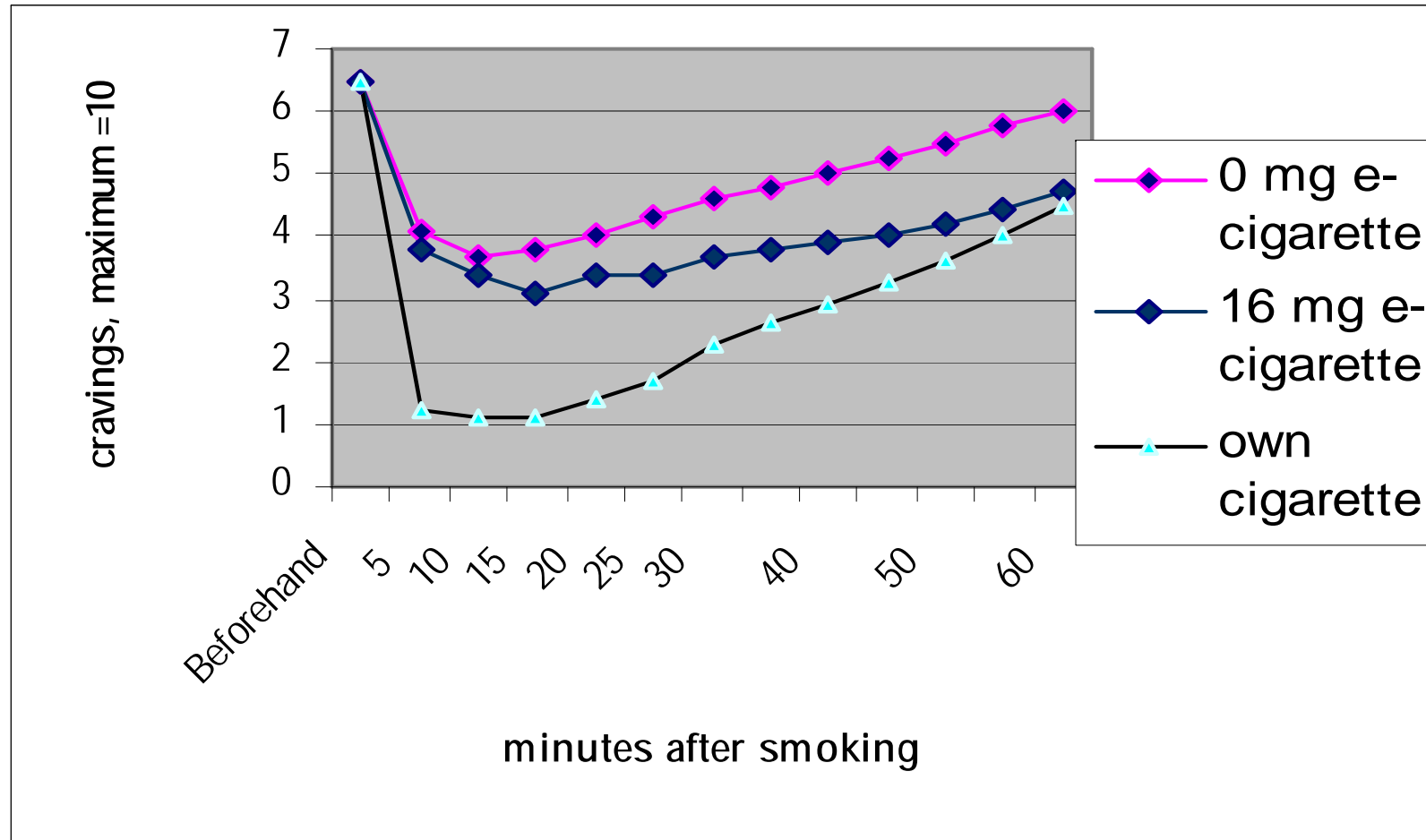
- by Clinical Trials Research Unit University of Auckland, 2008. N=40.
- No previous experience using e-cigarette. Norms not known for e-cig puffing.
- After overnight abstinence, inhale product.
- Ask “*How much do you want a cigarette right now?*” Marked on scale 0 to 10.
- Blood nicotine over 1 hour. N = 9
- Observed for 8 hours, reactions noted.



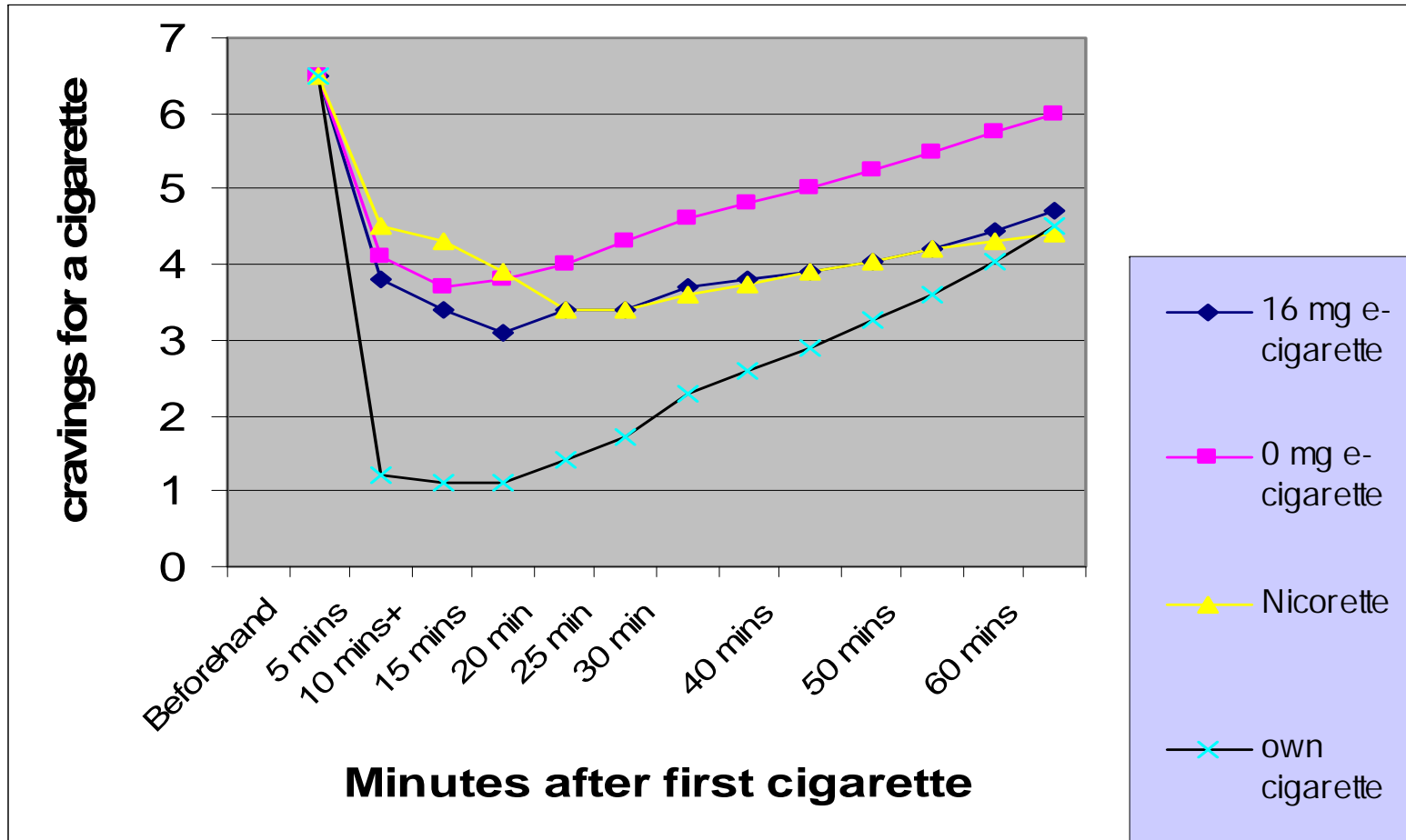
# **Efficacy. Does the e-cigarette relieve cravings?**

- When puffed like a cigarette for 5 minutes, relieves cravings, but less than own cigarette.
- Smoking reduced to 2 cigarettes on first day (without anyone intending to quit)
- E-cig acts more rapidly than Nicorette inhaler, but not as rapidly as own cigarette.

# Cravings relief by product, after overnight abstinence from smoking



# Cravings relief from medicinal inhaler, e-cigarette, own cigarette

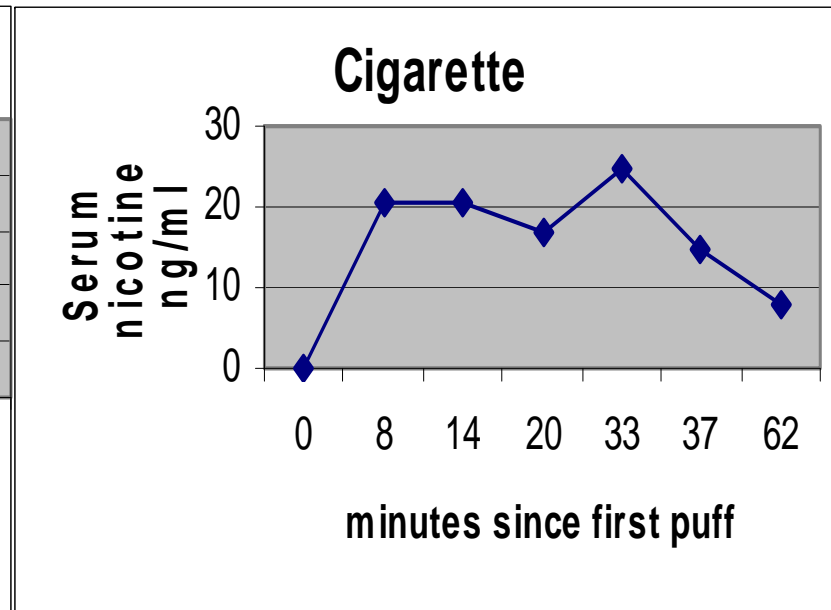
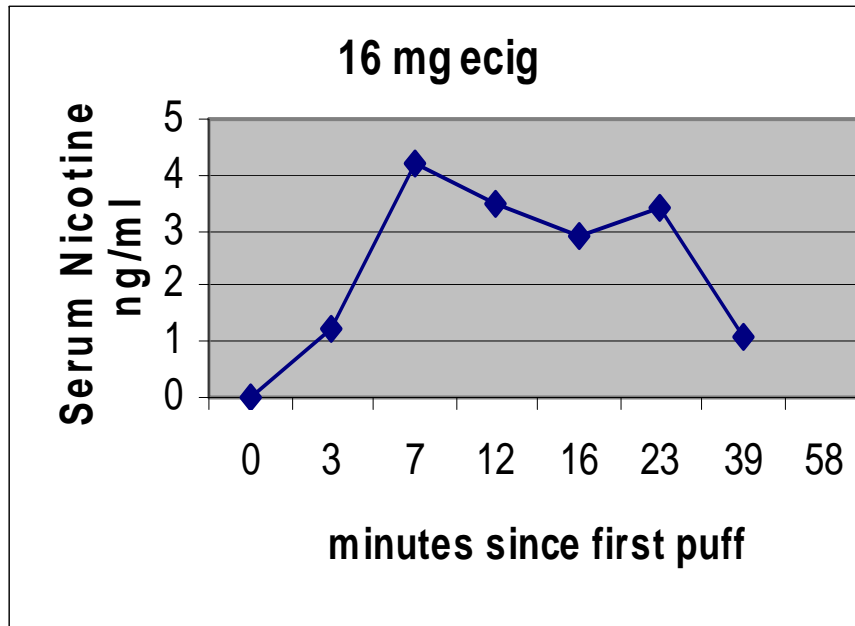


# Pharmacokinetics

Cigarettes puffed 5 mins;  
Nicorette puffed for 20 minutes.

	T max (minutes)	C max ng / ml
Own brand cigarette	14.3	13.4
Ruyan e- cigarette	19.6	1.3
Nicorette inhaler (10 mg)	32.0	2.1

# Serum Nicotine after inhaling



- S. Nicotine increases 4 ng/ml in 7 minutes in this e-smoker.
- S. Nicotine increases 20 ng/ml in 8 minutes in this smoker

# Patent law enforcement necessary for registration as a medicine

- Ruyan holds world patent applications for atomiser.
- Sales going to copycat companies, undercutting Ruyan's price.
- World sales were estimated at US100 million annually in 2008.
- Low cigarette prices in China make sales economic only in West.
- Ruyan has prosecuted several rivals successfully under IP law.
- Cigarette companies have the resources to improve reliability and nicotine delivery of the product, but cannot sell without a patent.
- No e-cigarette has been approved as a medicine by any regulator.
- Without enforcement of IP law by the patent holder in China and importing countries, even the patent holder cannot afford to register any e-cigarette as a medicine.
- No registration as a medicine expected for Australia and NZ for 3 years. Meantime personal-use imports permitted into NZ.